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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,285	08/08/2002	Roland Suck	MERCK 2386	8082

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,285

Applicant(s)

SUCK ET AL.

Examiner

Michael Szperka

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Please note that the examiner of record for your application has changed. To aid in paper matching, please address all future correspondence to Michael Szperka, Art Unit 1644, Technology Center 1600.

Applicant's response and amendment received February 14, 2006 is acknowledged.

Claims 1-8 are canceled.

Claims 9-25 are pending and are under examination in the instant office action.

Applicant is thanked for the submission of the document designated as "BB" on the IDS received 1/28/03. This reference has been listed on the 892 form that accompanies this office action.

Priority

2. It is noted that applicant has supplied a certified English language translation of the German foreign priority document 19939982.4, and this document appears to support the instant claimed invention. As such, it appears that the appropriate date for examination of the instant claims in relation to the prior art is 08/24/1999, the date on which the foreign priority document was filed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. The rejection of claims 9-25 under 35 U.S.C. 102(a) as being anticipated by Suck et al. (reference BC on the 1/28/03 IDS, see entire document) has been withdrawn due to applicant's perfection of the foreign priority claim in the reply received February 14, 2006 which removes this reference as prior art.

5. Applicant's response and amendments received February 14, 2006 have successfully removed all rejections of record. However, upon reconsideration of the instant claimed invention new grounds of rejection have been set forth as detailed below.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claims 9 and 24 recite methods for obtaining essentially pure pollen allergen, but the specification does not appear to define the metes and bound of "essentially pure." As such a skilled artisan would not be apprised as to the level of contamination due to the presence of unwanted materials that are found in the products obtained by performing applicant's method and as such could not determine if the method had been performed correctly. Amendment of the claims to recite, for example, "A method of purifying Group 1, 2, 3..." could be beneficial in overcoming this rejection.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 9-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of purifying group 1, 2, 3, 10, and 13 grass allergens from an aqueous pollen extract by using hydrophobic interaction chromatography followed by gel filtration chromatography and cation exchange chromatography as is delineated in Figure 1 of the instant specification using the specific buffer and running conditions detailed in the working example found on pages 6-8 of the instant specification, does not reasonably provide enablement for a generic method of purifying group 1, 2, 3, 10 and 13 grass allergens using hydrophobic interaction, gel filtration and cation exchange chromatography wherein the buffers to be used and the order of the purification steps are unspecified. The specification does not

Art Unit: 1644

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's specification provides a flowchart in Figure 1 that indicates the order in which process steps to be performed and indicates the products expected to be obtained at each step, while the text of the specification on pages 6-8 provides details concerning the buffers and other experimental conditions used in the working example of isolating group 1, 2, 3, 10, and 13 allergens from the pollen of *Phleum pratense*, also known as Timothy grass. Applicant's claims are broader in scope than these teachings in that the order of the purification steps is not recited, nor are the buffers and other running conditions specified. It is noted that some claims, such as claim 14, do indicate that cation exchange is to be performed subsequent to gel filtration, but it does not appear to be clearly recited in any claim that hydrophobic interaction chromatography is to be used as the initial purification step. It is well known in the art that the order in which purification steps are performed can dramatically impact ultimate yield and purity of the end product (Williams, Overview of Conventional Chromatography, pages 8.1.1-8.1.9, see entire document). It is also known that the choice of buffering systems can be of critical importance for chromatographic separation, especially in hydrophobic interaction chromatography where the interaction between the immobilized ligand and the protein(s) to be purified are facilitated by the addition of salts which increase precipitation of hydrophobic compounds according to the Hofmeister series, and pH is also known to be an important separation parameter (Kennedy, R.M., Hydrophobic-Interaction Chromatography, pages 8.4.1-8.4.21, see entire document, particularly

Art Unit: 1644

pages 8.4.4 and 8.4.5). The choice of salts and pH are also known to be of great importance in the practice of ion-exchange chromatography (Williams et al., Ion-Exchange Chromatography, pages 8.2.1-8.2.30, see entire document particularly pages 8.2.2 and 8.2.3), while pore size and flow rate are of utmost importance in gel-filtration chromatography (Hagel L., Gel-Filtration Chromatography, 8.3.1-8.3.30, see entire document, particularly pages 8.3.2 to 8.3.6). As such, it appears that knowledge of the conditions used in the purification protocol are essential in order to obtain an essentially pure grass allergen as is recited in the preamble to the claims.

Therefore, given the breadth of applicant's claimed method, the lack of clear indication of the order in which the process steps are to be performed, the art recognized importance of the ordering of such steps in order to achieve successful purification, the lack of a recitation of the buffer pH and composition and other parameters that are known in the art to be of crucial importance in chromatographic purification protocols, a skilled artisan would be unable to practice the full breadth of applicant's claimed method without first conducting an undue amount of research.

Claim Objections

10. Claims 10, 22, 23, and 25 are objected to because they contain the genus and species names of various plants, such as *Phleum pratense*, yet the names of these organisms are not italicized in the claims as is customarily done in scientific affairs.


Art Unit: 1644

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
April 24, 2006


Patrick J. Nolan, Ph.D.
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4/27/06